ITC Japan-Canada Heated Tobacco Products Survey Technical Report

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ITC Japan-Canada Heated Tobacco Products Research Team

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1 SUMMARY AND OVERVIEW OF THE PROJECT

1.1 Introduction

The International Tobacco Control Policy Evaluation Project (ITC Project) was established in 2002 to monitor and evaluate key health policies implemented in countries that are signatories to the Framework Convention on Tobacco Control (FCTC)—the first-ever international public health treaty—that was adopted in May 2003 by all 192 member states of the World Health Organization. Over the past two decades, the ITC Project has provided invaluable data to inform governments and other stakeholders on whether public health policies designed to reduce the health, economic, and societal costs of tobacco use throughout the world, are effective. The ITC Project conducts longitudinal surveys in representative cohorts in 29 countries.

The ITC Japan-Canada Heated Tobacco Products (JCH) Project officially commenced in April 2018 with planning and survey development, and the fieldwork, which consisted of both a survey and a urine collection component in two countries, Canada and Japan, was conducted from September 12, 2018 to February 27, 2019. The purpose of the study is to examine consumer use and toxicant exposures from new heated tobacco products (HTPs), primarily iQOS, Ploom TECH, and glo, which have recently been introduced into the marketplace in the Japan, Canada, as well as a number of other countries.

1.2 Main objectives and research questions

The objectives of the ITC JCH Project were:

1) Compare levels of tobacco-related biomarkers and toxicants (including nicotine and carcinogens) among eight groups across two countries: 1) current cigarette-only smokers; 2) current iQOS-only users; 3) dual iQOS+cigarette users; 4) never nicotine users; 5) e-cigarette (EC)-only users (Canada only); and 6) dual EC + cigarette users (Canada only); 7) Other exclusive HTP users (Ploom TECH and glo – Japan only)
2. Examine and compare consumption patterns and reasons for using HTPs among current iQOS users in Japan and Canada, and Ploom TECH, and glo users in Japan.
3. Examine levels of tobacco-related biomarkers and toxicants (including nicotine and carcinogens) in HTP users vs. EC users, across level of use (exclusive vs. dual).

1.3 Overview of project

- The ITC JCH Project is a special project, supported by the US NCI supplemental grant #3P01CA200512-03S1 under the parent P01 Grant, P01 CA200512, "Evaluating How Tobacco Control Policies are Shaping the Nicotine Delivery Market".
- This research examines the exposure to metabolites of nicotine and tobacco-related carcinogens in iQOS, Ploom TECH and glo users relative to those who use other non-combustable nicotine-containing products (ECs) and ordinary cigarette-only smokers and non-nicotine users/never users via a urine sample and a 15-minute web survey of adults in Japan and Canada.
- Japanese respondents were recruited from Rakuten Insight's panel.
- Canadians respondents were recruited from CRC Research, Canada in collaboration with Rakuten Insight.
- Upon completion of the web survey, participants were sent a collection kit to provide a urine specimen, which was analyzed for a panel of established exposure biomarkers relevant to tobacco/nicotine use.

2 SURVEY MEASURES AND PROGRAMMING

2.1 Survey development

The survey development process comprises four main phases:

1) determining survey content, and
2) operationalization of survey content,
3) translation, and
4) translation review and verification.

2.1.1 Survey content and operationalization

- During Phase 1 of the survey development process, the research investigators, project management team, and the survey management team (SMG) determined which topics were most important to include in the survey, and then developed the detailed survey questions necessary to measure relevant constructs using the existing framework of the ITC database of questions. HTP-related material, relatively new to ITC surveys, required the creation of new question sets. These questions were adapted from previously existing questions focussed on other nicotine and tobacco products.
- In Phase 2, the operationalization of survey development, involved comprehensively and iteratively reviewing, and revising the survey to ensure that routing, question wording, response options, and all other survey elements are refined and cross-referenced for consistency, clarity, and accuracy. At the conclusion of Phase 2, the final draft of the survey was generated by SMG and sent to Rakuten Insight for programming and testing.
- During the period when the survey firm programmed and tested the survey, additional revisions were made in consultation between Rakuten Insight and SMG, until a fieldwork version of the survey was achieved. The fieldwork version of the survey was sent to SMG by the firm and is retained in the SMG database. The updated last version of the survey in the database was later used to cross-reference with the data set.

2.1.2 Translation and translation review/verification

- The team developed the JCH survey content and specifications in English initially. The final English JCH survey was then translated into Japanese by Rakuten Insight and Canadian French by ITC personnel fluent in the language, as per specifications provided by the research team.
- For the survey in Japan, after the initial translation from English into Japanese had been completed and checked internally by the Rakuten Insight translator(s), the Japanese translation of JCH was then verified by a native Japanese translator, and issues were identified, discussed, and resolved to confirm the Japanese translation met the research team's standards for the highest possible degree of accuracy.
- For the Canadian survey, the translation from English into Canadian French was verified internally by a native French Canadian at the University of Waterloo.

2.2 Survey content

The ITC JCH Survey content was developed to assess the research objectives described in Section 1.2 as well as measure other constructs necessary to meet the survey objectives. These include demographic, and

social and psychological factors relevant to models of behaviour change, as well as content to meet logistical requirements for the survey.

The specific ITC JCH Survey content included the following:

- Information about the survey, time commitment, contact information for ethical concerns or survey-related concerns, and an explicit consent screen.
- Screening section that assesses age, gender, ethnic background (Canada only), smoking status, heat-not-burn product use status, and in Canada, EC use status.
- The following question categories were asked for the following product types: Cigarettes; iQOS; ECs (Canada only); and, other HTPs (Ploom TECH and glo – Japan only):
    - Duration of use, dependence, brand choice, purchase, product perception, beliefs about quitting, psychosocial beliefs, and perceived risk.
- Other questions: product susceptibility and policy support.
- Product comparison questions were asked to measure perceived differences between the products outlined above. These included questions comparing:
    - iQOS to cigarettes
    - iQOS to ECs (Canada only)
    - ECs to cigarettes (Canada only)
    - Other HTP (Ploom TECH and glo) to iQOS (Japan only)
    - Other HTP (Ploom TECH and glo) to cigarettes (Japan only)
- Demographic questions (e.g., age, gender, education, income, socio-economic status).

2.3 Survey programming and testing

Rakuten Insight used the JCH specifications (provided in Microsoft Word format) to program the JCH English Survey using Confirmit Computer-assisted Web Interview (CAWI) Software.

Rakuten Insight worked closely with the research team to test the English survey CAWI program and survey quotas. The research team provided signoff on the JCH English Survey program that met pre-determined standards prior to beginning data collection.

After receiving signoff on the Japanese and French translations, Rakuten Insight overlaid the translations into the CAWI program (originally programmed in English). The translated CAWI programs were then systematically tested to ensure they were functioning as intended and free of errors.

2.4. Timeline

Table 1: Summary of the JCH survey development timeline.

Task	Start date	End date
Survey content determined	April 2018	June 2018
Operationalization	June 1, 2018	July 20, 2018
Translation (includes discussion)	July 23, 2018	August 10, 2018
Translation review and checking	August 13, 2018	August 31, 2018

3 STUDY SAMPLE

3.1 Overview of Wave 1 ITC JCH Survey sample and quotas

The target sample size for the JCH Survey was 360 Japanese adult cigarette smokers, iOQS-only users, dual users of cigarette + iOQS, a combined 'Other HTP-only' user group consisting of glo-only users and Ploom TECH-only users, and non-smokers; and 450 Canadian adult cigarette smokers, iOQS-only users, dual users of cigarette smokers + iQOS, EC-only uesrs; dual users of cigarette smokers + EC-users, and non-smokers. Tables 2 and 3 provides the sub-sample definitions, targets, and achieved sample.

3.1.1 Canada

The target sample size for the JCH Survey in Canada was 450 respondents, broken down in to the following categories of user types:

Table 2: Target Sample in Canada

Canada					
	User Group	**N**	**Definition 1**	**Definition 2***	**Definition 3****
1	Exclusive Cigarette Smoker	75	Daily use for past 3 months	N/A	N/A
2	Exclusive iQOS User	75		Use for at least 5 days in a week for the past 3 months	N/A
3	Exclusive EC User	75		N/A	N/A
4	Dual User of iQOS+Cigarette	75	Daily use of both products for past 3 months	Daily use of iQOS and weekly use of cigarettes for past 3 months	Weekly use of iQOS and daily use of cigarettes for past 3 months
5	Dual User of EC + Cigarette	75		Daily use of ECs and weekly use of cigarettes for past 3 months	N/A
6	Never or Non-User	75	Never use or has stopped use of any tobacco product (including HTP) for the past 12 months.	N/A	N/A
	Total	**450**			
	Gender Quota by ethnicity	**White**		**155 males; 155 females**	
		Non-White		**70 males; 70 females**	

*Due to the novel nature of iQOS and ECs, conditions were in place for weakening the screening criteria, should recruitment under the first definition fall short.

** As dual iQOS + cigarette respondents remained difficult to recruit even under the looser "Definition 2", a third definition was created in the middle of fieldwork to boost recruitment.

3.1.2 Japan

The target sample size for the JCH Survey in Japan was 360 respondents, broken down in to the following categories of user types:

Table 3: Target Sample in Japan

Japan				
	User Group	**N**	**Definition 1**	**Definition 2**
1	Exclusive Cigarette Smoker	75	Daily use for past 3 months	N/A
2	Exclusive iQOS User	75		
3	Exclusive Ploom TECH User	60		
4	Exclusive glo User			
5	Dual User of iQOS + Cigarette	75	Daily use of both products for past 3 months	Daily use of iQOS and weekly use of cigarettes for past 3 months
6	Never or Non-User	75	Never use or has stopped use of any tobacco product (including HTP) for the past 12 months.	N/A
	Total	**360**		
	Gender Quota	**2:1 (Male:Female) approx. 240 males; 120 females**		

3.1.3 Inclusion/exclusion criteria and quotas

For Japan, Rakuten Insight used demographic profile information about their existing panelists to inform which panelists would be invited to the survey.

For Canada, Rakuten Insight used demographic profile information provided by partner research firm, CRC Research, to inform which panelists would be invited to the survey.

Once invited to the survey, the panelists first completed screening to ensure they met the following inclusion criteria:

- Participants were adults aged 18 years or older;
- Participants met the definition for one of the four user types specified in Tables 2 or 3 respective of country;
- The quota for the panelist's specifications (i.e., user type, gender, and in Canada, ethnicity) was still open.

The study exclusion criteria were:

- Those younger than 20 years old;
- Those who are dual or multi-product users who do not fit within Table 2, Groups 4 or 5, or Table 3, Group 5;
- Those who have used other tobacco products in the last three months, including pipe, cigars, cigarillos, hookah, snus, chewing tobacco, or dissolvable tablets;
- Those who have used NRT in the last three months;
- Those who have used any recreational drug within the last three months, including marijuana;
- Those who have been diagnosed with or treated for any of the following in the last 12 months:
    - Kidney disease
    - Cancer
    - Drug dependency
    - Alcohol dependency
    - Psychiatric conditions other than anxiety or depression;

- Those who are currently pregnant or breast feeding;
- Corresponding quota to panelist's specifications are full.

The strict exclusion criteria was critical to the urine analysis component of the study.

3.1.4 Description of sampling frame

- Canada
  - The subsample groups in Canada were recruited by CRC Research on behalf of Rakuten Insight. Subsample groups were recruited via offline methodology, a mix of panel usage, referrals, and consumer lists.
- Japan
  - The sampling frame in the ITC JCH Survey was Rakuten Insight's Japan web panel. All of the subsample groups were recruited from Rakuten Insight's Japan panel(s).
  - Rakuten Insight provided the following description of their panel(s): The ITC JCH Survey was conducted with Rakuten Insight's proprietary online panel in Japan. The online panel is actively managed in-house with a dedicated panel management team in Tokyo, and utilized for market research purposes only. Recruitment for the panel is conducted on a daily basis, tapping into users of Rakuten services (e.g. e-commerce, credit cards, insurance, mobile services, etc.), as well as other online resources such as affiliates, email and banner recruits in order to maintain a panel as consistent as possible with the general population. Panelists are pre-profiled with a series of questions which in turn can be used as pre-targeting variables (e.g. smoking, HTP usage, etc.). Panelists receive email invitations and also have the option of logging into their proprietary panel site to access the survey they are invited to participate in. Details available at: https://www.insight.rakuten.com/

4 RECRUITMENT AND INTERVIEW PROCEDURES

4.1 Contact and recruitment procedures

4.1.1 Recruitment strategy

- Phase 1 invitation emails: Invitation emails were sent strategically to sample those identified as probable tobacco users in order to fill the three (Japan) or four (Canada) tobacco user subsample quotas (i.e., quotas for exclusive cigarette smokers, exclusive EC users (Canada only), HTP (exclusive iQOS, Ploom TECH, and glo) users, and dual users were to be filled first), before the non-user quota.
- Phase 2 invitation emails: After the three tobacco user subsample quotas (i.e., quotas for exclusive cigarette smokers, exclusive EC users (Canada only), HTP users (exclusive iQOS, Ploom TECH, and glo), and dual users were filled, then invitations were sent out that strategically targeted non-users to fill the remaining open positions in the non-user quota.

4.1.2 Invitations and reminders

- Rakuten Insight for Japan and CRC Research for Canada invited respondents to the JCH Survey by sending them a standard email invitation that informed the panelists of the survey length and that they would receive the standard incentive for a 15-minute web survey.
- Per standard procedures, Rakuten Insight (Japan) and CRC Research (Canada) sent one email invitation and up to two reminders to panelists who had been pre-identified as being potentially eligible for the Survey. Once the quotas had been achieved, the web survey would close.
- Panelists were able to ignore the emails, or contact Rakuten Insight to refuse the study or unsubscribe from the panel at any time.

4.2 Fieldwork timeline

The ITC JCH Survey was conducted from September 12 to October 30, 2018 in Canada, and from November 14, 2018 to January 31, 2019 in Japan.

4.3 The survey experience and interview duration

The ITC JCH Survey was designed to have the look and feel of a typical Rakuten Insight survey, with some branding to identify the survey as an ITC survey. The Confirmit software automatically rendered the on-screen formatting to adapt to the respondent's device type (desktop/tablet vs. mobile device) so that text and visual elements would be appropriately placed on the screen to ensure an optimal survey-taking experience.

The ITC JCH Survey began with a screening section that assessed panelists' eligibility (based on user type, gender, and in the case of Canada, ethnicity quotas) and determined which survey questions (related to user type) would be asked throughout the survey. Thus, panelists experienced a tailored survey within a single programmed instrument, relevant to their current tobacco use pattern.

Consent screens provided information about the survey, time commitment, contact information for ethical concerns or survey-related concerns, and then the panelist was required to provide consent to complete the survey. Respondents were able to navigate back to previous questions to change a response. Respondents were also able to stop the survey and login to finish at a later time without losing any data.

Questions were primarily multiple choice format and included one question per page. Some questions had a check list or grid format, which was modified by the survey software depending on the device type that

the respondent used (i.e., desktop vs. a mobile phone). A small amount of questions with the 'Other-specify' format, required respondents type open text responses.

Respondents were required to submit their completed survey in order for their survey record to be considered 'complete'. Item non-response was acceptable, provided that: the majority of questions were answered, 'essential questions' used for eligibility were answered, and the panelist had submitted their survey.

The median length of the survey interview was 15 minutes for the valid complete records.

4.3 Assigning disposition codes

Disposition codes were used to track the outcomes of survey respondents. Temporary Disposition Codes were applied to respondents who did not complete the survey within one session. Final dispositions codes were assigned to each record (see *Section 7 Disposition Codes*).

Three types of disposition codes were used in the study: 1) disposition codes programmed into the survey script, 2) disposition codes entered by the survey firm, and 3) dispositions derived at the end of fieldwork (see **Section 7 Disposition Codes**).

Each completed survey record was further sub-coded as being completed on a desktop/tablet device vs. a mobile device vs. being undefined (not possible to classify).

4.4 Study incentives

- Upon submitting a completed survey, survey respondents were given:
    - In Japan, the equivalent of $20 USD in e-points.
    - In Canada, a cheque for $25 CAD.
- Upon submitting a completed survey, survey respondents were informed that an additional incentive would be given upon collection of their urine sample:
    - In Japan, the equivalent of $75 USD in e-points.
    - In Canada, a cheque for $125 CAD.

5 SURVEY FIELDWORK

Survey fieldwork began in Canada several weeks before it began in Japan. Conceptually, this was due to the difference in recruitment methodologies between the two countries. Canadian recruitment was offline. As described in 3.1.4, recruitment was a mixture of panel usage, referrals, and commercial lists. As part of the Rakuten Insight panel(s) in Japan, demographic and basic tobacco usage information was readily accessable to the survey firm, meaning a much shorter and more targeted invitation period.

As such, fieldwork dates varied between countries:

Table 4: Fieldwork start and end dates

	Survey Start Date (Local Time)	Survey End Date (Local Time)
Canada	September 12, 2018	October 30, 2018
Japan	November 14, 2018	January 31, 2019

**paused survey from December 19, 2018 ~ January 23, 2019*

The total number of respondents in each country, by user group were as follows:

Table 5: Total respondents completing the JCH Survey in Canada, by user group

Canada	Survey Completes		
Group Definition	**Male**	**Female**	**Total**
iQOS Only	1	0	1
Cig Only	40	36	76
iQOS + Cigarette - Definition 1 (Daily iQOS user + Daily Cigarette user)	3	3	6
iQOS + Cigarette - Definition 2 (Daily iQOS user + Weekly Cigarette user)	0	0	0
iQOS + Cigarette - Definition 3 (Weekly iQOS user + Daily Cigarette user)	0	0	0
EC Only	15	17	32
EC + Cigarette - Definition 1	48	20	68
EC + Cigarette - Definition 2	4	7	11
Non/Never-User	27	52	79
Total	137	135	272

Table 6: Total respondents completing the JCH Survey in Japan, by user group

Japan	Survey completes		
Group Definition	**Male**	**Female**	**Total**
iQOS only	45	34	79
Cigarette only	46	29	75
iQOS + Cigarette dual users	64	14	78
glo only	34	11	45
Ploom TECH only	14	2	16
Non-users	45	30	75
Total	**248**	**120**	**368**

5.1 Recruitment challenges in Canada

While recruitment of exclusive cigarette smokers, dual EC + cigarette users, and non-users occurred with little issue, it became clear quickly after fieldwork began that the recruitment of iQOS only, dual iQOS + cigarette users, and EC-only users were falling well below expectations.

As described in Section 3.1.1, there were multiple usage definitions built into the recruitment process to make it easier to successfully screen respondents into the ITC JCH Survey. To speed up recruitment of dual iQOS + cigarette users, screening shifted to Definition 2: (Weekly cigarette smoker + daily iQOS user) on September 24, 2018. It was also agreed at this time to build a third definition of dual user (Weekly iQOS user + daily cigarette smoker), to be used at a later date, should Definition 2 fail to effectively increase recruitment.

On September 26, 2018, it was agreed to relax the definition of an exclusive iQOS user to allow for those who use almost every day, rather than every day. The criteria (as outline in Section 3.1.1), was for an iQOS only user to use the product at least 5 of the 7 days in a week for at least 3 months. These changes to the screening criteria were implemented on October 9, 2018. In addition, prior to the launch of the fieldwork in Canada, marijuana usage was legalized, which resulted in survey disqualification of many participants.

Despite relaxing the relaxing of screening requirements, recruitment difficulties in Canada persisted and the decision was made on October 30, 2018 to close down the Canadian arm of the ITC JCH Survey.

6 QUALITY CONTROL

6.1 Fieldwork monitoring and progress reports

- Throughout fieldwork, Rakuten Insight closely monitored survey activity and ensured a smooth implementation.
- Rakuten Insight provided weekly fieldwork reports and an analysis of next steps with respect to the survey recruitment strategy.

6.2 Survey completes vs. partial completes

- The definition of a "survey complete" is the survey record for a panelist who started the survey, completed the survey questions, perhaps endorsing "prefer not to answer" for a reasonable proportion of questions, and then chose to 'submit the survey' after the last survey question.
- Survey response data for survey completes were checked using the criteria defined in Section 6.3. Records that passed the checks were considered valid completes.
- Survey response data for partially completed survey records (defined as records for which the panelist started the survey but did not hit submit at the end of the survey) were not included in the final data set.

6.3 Identification and removal of invalid records from the data set

- Rakuten Insight and the research team data analyst(s) systematically analysed submitted survey records to determine which records met the established criteria for providing invalid data on the basis of 'speeding through the survey', i.e., being a 'speeder'.

6.4 Data cleaning and topline frequencies

- After fieldwork was completed, Rakuten Insight cleaned the data and then transferred the cleaned data to the ITC Project.
- ITC Project analysts completed further data cleaning, weights construction, and conducted initial descriptive analyses, including generating topline frequencies.

6.5 Translation review and verification

- Standard procedures at ITC include validating the translation against the fieldwork-version of the survey. This process was conducted by an independent reviewer fluent in Japanese and English for Japan survey and by an ITC personnel fluent in Canadian French and English for Canada survey.

7 DISPOSITION CODES FOR ITC JCH SURVEY

Table 7: Replenishment/New Recruits Disposition Codes

Replenishment/New Recruits Disposition Codes			
DMC Code	**Type*1**	**Description**	**Comment**
Interview			
P-A1	P	Selected respondent completes the entire survey; maybe skipping or refusing to answer a few questions	
Eligible, non-interview			
P-B19	E	Respondent completed eligibility questions and was deemed to be eligible, then started to answer the survey but did not complete the survey	This is an important disposition code, and we expect that many individuals will fall into this category
P-B90	M	Any other reason why interview was not completed, but eligibility was confirmed by respondent	Unlikely to be used, but left in as a precaution
Unknown eligibility, non-interview			
P-C11.1	P	Respondent refuses, can't answer or doesn't know his/her DOB or age; thus unknown if he/she is eligible	
P-C11.2	P	Respondent refuses, can't answer or doesn't know his/her gender; thus unknown if he/she is eligible	Note that there are no gender quotas and that both males and females are eligible. However, this is an essential question, and respondents refusing to answer it will be terminated. Because this termination happens early in the survey, essential eligibility questions will not be asked. For this reason, the eligibility status of respondents refusing to answer this question is unknown.
P-C11.5	P	Respondent refuses, can't answer or doesn't know his/her cigarette smoking status; thus unknown if he/she is eligible	
P-C11.6	P	Respondent refuses, can't answer or doesn't know his/her e-cigarette/vaping status; thus unknown if he/she is eligible	
P-C11.7	P	Respondent refuses, can't answer or doesn't know his/her iQOS status; thus unknown if he/she is eligible	
P-C11.8	P	Respondent refuses, can't answer or doesn't know his/her heat-not-burn products other than iQOS status; thus unknown if he/she is eligible	
P-C11.10	P	Respondent refuses, can't answer or doesn't know his/her health relative products status; thus unknown if he/she is eligible	
P-C11.11	P	Respondent refuses, can't answer or doesn't know his/her medical/mental disease	

		diagnosis status; thus unknown if he/she is eligible	
P-C11.12	P	Respondent refuses, can't answer or doesn't know his/her alcoholic drinks status; thus unknown if he/she is eligible	
P-C11.13	P	Respondent refuses, can't answer or doesn't know her pregnant/breast-feeding status; thus unknown if he/she is eligible	
P-C13	P	Respondent refuses at consent; thus unknown if he/she is eligible; thus unknown if he/she is eligible	
P-C70	M	Invalid email or email bounce back	
P-C72	E	Respondent never logged into system to start the survey (but there was no email bounce back/invalid)	This is an important disposition code, and we expect that many individuals will fall into this category
P-C75	P	Respondent refuses to provide email	Unlikely to be used, but left in as a precaution
P-C90	M	Other reason why unknown eligibility	Unlikely to be used, but left in as a precaution
Not eligible			
P-D10	P	Respondent is out of sample	For example, respondent does not reside in Canada or Japan
P-D70	P	Respondent is too young (i.e., < 20 years old)	
P-D72	P	Respondent doesn't meet the eligibility criteria on smoking or tobacco use	
P-D73	P	Respondent doesn't meet the eligibility criteria on health status	
P-D75	M	Respondent doesn't have an email address	Unlikely to be used, but left in as a precaution
P-D80.1	P	Quota for group 1 (iQOS only) full	
P-D80.2	P	Quota for group 2 (Cigarette only) full	
P-D80.3	P	Quota for group 3 (iQOS and Cigarette) full	
P-D80.4	P	Quota for group 4 (e-cigarette only) full	Only applies to Canadian respondents
P-D80.5	P	Quota for group 5 (E-cigarette and Cigarette group) full	Only applies to Canadian respondents
P-D80.6	P	Quota for group 6 (glo only) full	Only applies to Japanese respondents
P-D80.7	P	Quota for group 7 (Ploom TECH only) full	Only applies to Japanese respondents
P-D80.8	P	Quota for group 8 (non/never) full	
P-D90	M	Any other reason why respondent is not eligible	Unlikely to be used, but left in as a precaution

Notes:

*1 Type of disposition codes:

P = disposition code programmed into the survey

M = disposition code to be recorded by the fieldwork manager or supervisor

E = disposition code to be derived at the end of fieldwork

8 COOPERATION AND RESPONSE RATES FOR ITC JCH SURVEY

Table 8: Cooperation and Response Rates

		Canada *12		Japan *12		Overall	
		Freq	%	Freq	%	Freq	%
8	A – Interviewed						
9	Completed survey and provided PII*1	276	31.1%	369	1.9%	645	3.1%
10	Completed survey, but didn't provide PII*2	5	0.6%	443	2.3%	448	2.2%
11	Total (interviewed)	281	31.7%	812	4.1%	1,093	5.3%
12							
13	B – Eligible, but not interviewed						
14	Refusal/breaks off	21	2.4%	9	0.0%	30	0.1%
15	Other	0	0.0%	0	0.0%	0	0.0%
16	Total (eligible but not interviewed)	21	2.4%	9	0.0%	30	0.1%
17							
18	C – Unknown if eligibility (not interviewed)						
19	Logged into system to start survey (once or more)	15	1.7%	5,660	28.9%	5,675	27.7%
20	Estimated number of eligible and quota not full*3	7	0.8%	956	4.9%	963	4.7%
21	Estimated number of not eligible or quota full*4	8	0.9%	4,704	24.0%	4,712	23.0%
22	Never logged into system to start survey	229	25.8%	9,652	49.2%	9,881	48.2%
23	Estimated number of eligible and quota not full	105	11.8%	1,630	8.3%	1,735	8.5%
24	Estimated number of not eligible or quota full	124	14.0%	8,022	40.9%	8,146	39.8%
25	Total (unknown if eligible)	244	27.5%	15,312	78.1%	15,556	75.9%
26							
27	D – Not eligible						
28	Out of sample	0	0.0%	0	0.0%	0	0.0%
29	Respondent is not eligible	326	36.8%	3332	17.0%	3,658	17.9%
30	Quota full	15	1.7%	140	0.7%	155	0.8%
31	Other	0	0.0%	0	0.0%	0	0.0%
32	Total (not eligible)	341	38.4%	3,472	17.7%	3,813	18.6%
33							
34	Total sample with final disposition	887	100%	19,605	100%	20,492	100%
35							
36	Estimated eligibility rate*5	48.1%		19.8%		23.5%	
37	Estimated proportion for which quota was full*6	4.7%		14.6%		12.1%	
38	Response rate*7,*11	67.9%		23.8%		28.6%	
39	Cooperation rate*8,*11	93.0%		98.9%		97.3%	
40	Response rate*9,*11,*12	66.7%		10.8%		16.9%	
41	Cooperation rate*10,*11,*12	91.4%		44.9%		57.4%	

Notes:

*1 Those respondents completed the survey, provided Personally identifiable information (PII) and were thus sent the sample kit

*2 Those respondents completed the survey, but refused to provided Personally identifiable information (PII) and thus no sample kit was sent to them

*3 Estimated number of respondents that would have been eligible and for which the corresponding quota would not have been full

Formula: row 19 x row 36 x (1 - row 37), rounded to the nearest integer

*4 Formula: row 19 - row 20

*5 Estimated proportion of individuals that were eligible (i.e., age 20 & older and meet smoking/tobacco use criteria)

Formula: 1 - row 29 / (row 11 + row 16 + row 29)

*6 Estimated proportion of individuals that would have been terminated because the corresponding quota was full

Formula: row 30 / (row 11 + row 16 + row 30)

*7 Response rate where respondents that completed the survey but didn't provide PII are treated as complete

Formula: row 11 / (row 11 + row 16 + row 20 + row 23)

*8 Cooperation rare where respondents that completed the survey but didn't provide PII are treated as complete

Formula: row 11 / (row 11 + row 14)

*9 Response rate where respondents that completed the survey but didn't provide PII are treated as refusals

Formula: row 9 / (row 11 + row 16 + row 20 + row 23)

*10 Cooperation rare where respondents that completed the survey but didn't provide PII are treated as refusals

Formula: row 9 / (row 11 + row 14)

*11 Though respondents that completed the survey but didn't provide PII (row 10) actually completed the survey and were thus assigned a disposition code of PA-1, it is probably best to treat them as refusals since this meant that it was impossible to send them the sample kit, which was the key aim of this study

*12 Recruitment in Canada used mostly offline recruiting, which involved pre-screening prior to inviting respondents to the survey. This did not happen in Japan, where high volumes of invitations were sent. The different in methodology yielded response rates and cooperation rates that are not comparable between the two countries

9 URINE COLLECTION

9.1 Urine Collection Kit Assembly

Urine kits were assembled at Roswell Park Comprehensive Cancer Center in Buffalo, New York, USA and shipped the University of Waterloo, Ontario, Canada where Research Assistants verified the contents of the kits to ensure that it had all necessary components. Each kit contained the following items:

- Two Falcon tubes
- Two absorbent sheets
- Two small sealable plastic bags
- One larger sealable plastic bag
- One Styrofoam insulated case
- One freezer gel pack pouch
- One cardboard box for shipping
- A return shipping envelope
    - In Canada, a FedEx UN3373 labelled shipping envelope
    - In Japan, a large plain manila envelope with pre-paid postage
- An information sheet on the project with consent form (Japanese in Japan; both French and English in Canada)
- Urine collection instructions (Japanese in Japan; both French and English in Canada)
- A pre-paid envelope for shipping the consent form back to the University of Waterloo

9.2 Urine Collection Kit Mail-out

9.1.1 Canada

Once a respondent completed their survey portion of the fieldwork, Rakuten Insight would quickly verify the survey for quality control and then send the respondent's contact information and SurveyID number to the University of Waterloo via a secure website. Any files containing contact information were password protected, and only those with permissions assigned from the site administrator could access the folders on the secure website.

The SurveyID number was then tied to a different corresponding urine collection kit ID that was labelled on the small sealable plastic bags, the cardboard shipping box, the information sheet, and the return shipping envelope. As survey ID and the urine collection kit ID did not match, the University of Waterloo maintained a Master List that tied the ID from the survey fieldwork to the ID on the urine collection.

Once a corresponding kit has been selected for the respondent, it was mailed to the participating respondent within 24 to 48 hours of survey completion. This timeline was important as it ensures the behaviours outlined in the survey correspond to the urine collected.

9.1.2 Japan

Once a respondent completed their survey portion of the fieldwork, their ID number was tied to a corresponding ID on the urine collection kit. As with Canada, these two IDs do not match, therefore it was

necessary for Rakuten Insight to maintain a Master List that ties the ID from the survey fieldwork to the ID on the urine collection kit.

Once a corresponding kit has been selected for the respondent, it was mailed to the participating respondent within 24 to 48 hours of survey completion. This timeline was important as it ensures the behaviours outlined in the survey correspond to the urine collected. Rakuten Insight used local Japanese courier Sagawa for shipping kits to and from respondents.

9.3 Urine Collection Instructions

For a detailed breakdown on the instructions received by respondents regarding urine collection, please refer to Appendix 2.1 for Canada, and Appendix 2.2 for Japan.

9.4 Sample Collection Card

At the time of collection, respondents were asked to fill out the following Sample Collection Card:

SAMPLE COLLECTION CARD

ID number [affix sticker here]:

DATE OF COLLECTION: _____ / _____ / _____ (YY/MM/DD)

TIME OF COLLECTION: _____am / pm

Please place this card in the box with your sample before sealing.

Reminder: When shipping back the sample to us, please do not include the signed consent in this package. Signed consent form should be sent separately in another return envelope.

9.5 Sample Return Shipping

The Urine Collection Instructions informed participants to collect and return their sample within five days of receiving their kit, the purpose being that again, it was most important that behaviour not change between the time of the survey and that of the urine collection. The Information Letter and Consent form explained that the Consent form and the sample must be returned separately. This was an ethics requirement ensuring that the urine is separate from any identifiable information contained within the consent form.

In Canada, the sample was shipped back to the University of Waterloo in an envelope marked for the transportation of human biosamples, UN3373 designation. This was not necessary in japan.

The Consent Form was shipped in a smaller envelope provided with the original shipment. Respondents were not considered complete until both the sample and the consent form had been received. Samples with no consent form could not be used in the analysis, as per ethics requirements, however, no such instances occurred.

9.6 Sample Unboxing and Storage

Upon receiving samples at both Rakuten Insight (Japan) and the University of Waterloo (Canada), samples are to be kept in a standard -20 degree Celsius freezer. Roswell Park Comprehensive Cancer Center provided cardboard freezer trays for storage of the urine tubes collected. These boxes allowed for maximizing the effectiveness of freezer storage and reduce the risk of leakage/damage to the sample containers. Each tray could hold up to 16 falcon tubes in a 4x4 grid.

Samples were unboxed by members of the research team and research assistants in Canada, and Rakuten staff in Japan. The following specimen handling instructions were followed:

Step 1: Inspect if there are no visible signs of damage or leakage on the outside of the kit return envelope, you may proceed with opening the envelope and removing the urine sample collection kit contained in the cardboard box.

Step 2: Open the envelope and inspect the cardboard box for any signs of damage or leakage.

Step 3: If no signs of damage or leakage are visible on the box, remove each of the two polypropylene tubes from the biospecimen transport bag. Each of the two urine samples in the kit will be contained in polypropylene tubes. Those two tubes will be placed in individual plastic zip top bags containing absorbent material that will help in containing any spills or leaks. Additionally, those two zip top bags will be placed in a larger biospecimen transport bag, which will also be filled with absorbent material. Although we do not anticipate any spills or leaks, these containment measures should keep any spills or leaks confined to a small area (inside one of the bags).

Step 4: Inspect the tubes while contained in the individual plastic zip top bags. Tubes should not be overfilled and the labels should be properly fixed on each tube.

If there are visible signs of leakage (urine spilled out of container and contained by the bags and absorbent material), reclose the box, put it in the freezer for later determination, and make a note in the log sheet* that the kit was returned damaged.

If the samples appear to be intact and free of damage, place upright (purple top up) into the freezer tray and place the tray in frozen storage.

Step 5: Use the log sheet* to note the receipt and condition of each sample.

Step 6: Discard the cardboard box, Styrofoam container, gel pack, and biospecimen bag safely and appropriately.

Step 7: When you receive the consent forms, please open the envelope and check to be sure the participant has signed the consent form. Use the log sheet to confirm the receipt of the informed consent form and whether or not it was signed, next to the columns for each of the two samples.

9.7 Total Samples returned

Urine collection began on September 13, 2018 and was officially closed on January 24, 2019 in Canada. For Japan, urine collection began on November 15, 2018 and was officially closed on February 27, 2019.

Table 9: Sample completes for Canada

Canada	Sample completes (Urine sample + consent form)		
Group Definition	**Male**	**Female**	**Total**
iQOS only	1	0	1
Cigarette only	35	30	65
iQOS + cigarette	2	2	4
E-cigarette only	14	15	29
E-cigarette + cigarette	36	17	53
Non user	26	44	70
Total	**114**	**108**	**222**

Table 10: Sample completes for Japan

Japan	Sample completes (Urine sample + consent form)		
Group Definition	**Male**	**Female**	**Total**
iQOS only	40	30	70
Cig only	38	22	60
iQOS+cig dual users	56	12	68
glo only	32	10	42
Ploom TECH only	12	2	14
Non-users	44	26	70
Total	**222**	**102**	**324**

9.8 Delinquent urine samples

Respondents were contacted to remind them to ship their urine sample if the sample had not been received two weeks after the date of survey completion. While this was not ideal, the research team decided that any urine samples received within one month of the survey completion date would still be accepted for analysis. Any samples that were received after one month would be destroyed. Respondents who had not shipped their urine sample more than one month from their survey completion date were no longer sent reminders.

9.9 Urine Sample Shipment to Roswell Park Comprehensive Cancer Centre

All urine analysis is handled by the lab at Roswell Park Comprehensive Cancer Centre, Buffalo, New York, USA. All samples were to be sent to Roswell Park in insulated boxes filled with dry ice to ensure the urine samples remained frozen during the shipment process. All shipments were required to follow IATA and CDC guidelines for non-infectious human specimens, including any and all proper labelling.

9.9.1 Canada

There were two main shipments of urine samples from the University of Waterloo to Roswell Park. The first shipment was sent on December 3, 2018 and contained 384 urine samples from 192 respondents. The remaining 60 samples from 30 respondents were shipped on January 28, 2019.

9.9.2 Japan

There were three main shipments of urine samples from Rakuten Insight Japan to Roswell Park. The first shipment was sent on December 17, 2018 and contained 298 urine samples from 149 respondents. The second shipment was sent on February 5, 2019 and contained 266 samples from 133 respondents. The remaining 102 samples from 51 respondents were shipped on March 4, 2019.

APPENDIX 1.1: ITC JCH EMAIL INVITATION TEMPLATE, CANADA

We are currently conducting a study on tobacco use from the International Tobacco Control Policy Evaluation Project, based out of the University of Waterloo. The ITC Project is conducting the study to determine the chemicals being absorbed in the body for people who use different types of tobacco and nicotine products. If you are a smoker, you may qualify to participate. Non- smokers may also qualify for the study as well. In order to determine if you would be eligible to participate in this study, we need you to complete the questions below. Those who are a potential fit for the study, will then be sent a questionnaire to determine if they qualify. Those who qualify will be invited to participate in the study and will be asked to begin immediately.

1) Which of the following best describes your smoking habits?

1	Exclusive Daily Users of Ordinary Cigarettes
2	Exclusive Daily Users of nicotine e-cigarettes (vapes)
3	Exclusive Daily Users of iQOS brand HNB product
4	Daily Dual User of E-Cigarette + Ordinary Cigarettes
5	Daily Dual User of iQOS + Ordinary Cigarettes
6	Never smoked
7	Smoked in the past, but do not currently smoke
8	Casual Smoker – 1 to 2 cigarettes a week

2) People in Canada come from many racial and cultural groups. Choose the group below that best applies to you.
    1. Caucasian
    2. South Asian (for example, East Indian, Pakistani, Sri Lankan, etc.)
    3. African Canadian
    4. Caribbean or West Indian
    5. Filipino
    6. Latino
    7. East Asian (for example, Chinese, Japanese, Korean)
    8. Southeast Asian (for example, Cambodian, Indonesian, Laotian, Vietnamese, etc.)
    9. Arab
    10. West Asian (for example, Afghan, Iranian, etc.)
    11. Aboriginal (for example, North American Indian, Métis, or Inuit)
    12. Other racial or cultural group

3) May we have your complete mailing address? We need this information as those who qualify and agree to participate will be sent a package in the mail with their kit and instructions for participation, and we will use this information as reference for verification purpose. Your response to the survey will not be tied directly to your personal information. Please be sure to include any apartment or unit number as well as your postal code. **NOTE – We cannot ship to a P.O. box.**

APPENDIX 1.2: ITC JCH EMAIL INVITATION TEMPLATE, CANADA

Rakuten email invitation:

Email Subject Invitation to the special survey: User Exposure to Toxicants from Vaporised Nicotine Products [PROJECT NUMBER]

Email Body:

[NAME],

Thank you very much for participating in the Rakuten surveys.

Warm welcome to the Special survey!

□□□
You are part of a special group of participants across Japan and Canada that is invited to participate in this research that will help policymakers and health professionals in forming future policies and programs on tobacco and other nicotine-containing products.

The International Tobacco Control (ITC) HNB Biomarkers Survey is a research of people's knowledge, attitudes, and behaviours about nicotine-containing products. Both "users" and "non-users" of nicotine-containing products are needed for this study.
□□□

This is a research study that involves:

- participating in this 15-minute survey during the next few days, and
- following the completion of the survey, submitting a urine sample from a kit supplied by Rakuten on behalf of the team of researchers.

If you qualify and fully complete this survey, it's extremely important that you also submit the urine sample. Kits will be sent to participating respondents within 7-10 days of completing the survey!

Please join the below survey.

****

- **Survey URL: [LINK TO SURVEY]**
    - Answering a survey can only be done once per person.

- Survey length: About 15 minutes. (Actual length may vary depending on contents)
    - Incentive: [**Rakuten min – max incentive**].

- Closing Date: Once the required number of survey and sample completions is reached.
- Incentive Awarded Date：Max 60 days after completing the survey
    - Depending on the survey, it may take longer than the above timing.

****

Please take note while answering surveys:

- Please make sure to review each question and answer choice carefully to make sure your answers are accurately selected.

- We suggest the below internet environment: [xx]

- We strictly adhere to the Privacy Policy in the Member Agreement. Please do not disclose any information you acquired in the survey to any third party, including posts to bulletin boards and blogs.

- Surveys that were emailed more than 2 weeks ago will not appear on your My Page. Please click the URL to answer the survey.
    - If the URL is cut off based on your email setting, please copy the whole URL and paste it into your browser address bar.
    - You may not enter the survey if the survey is already closed.

- You will not be able to reply to this email.

- Please go to FAQ for any questions.

APPENDIX 2.1: URINE COLLECTION SHIPPING INSTRUCTIONS, CANADA

INSTRUCTIONS: "WHAT TO DO"

Urine Collection and Shipping Instructions

CANADA

Collect a urine sample and ship it to the laboratory using these instructions.
1) If you receive the kit on <u>Saturday</u>, you need to freeze the gel pack until Monday morning, collect the urine on MONDAY morning and ship it on Monday morning along with the gel pack in the urine kit box. Complete and sign the consent form and mail it separately using the pre-paid envelop. **2) If you receive the kit on <u>Monday, Tuesday, Wednesday or Thursday</u>, you need to freeze the gel pack immediately, collect your urine the next day in the morning, and ship on the same day along with the gel pack in the urine kit box. Complete and sign the consent form and mail it separately using the pre-paid envelop.**
A cheque for 125.00 CAD will be mailed to you within 8 weeks after we receive the package.

THE BAG YOU RECEIVED INCLUDES:

1. Large envelope that contains the collection kit, and your unique ID sticker
2. "WHAT TO DO" Urine Collection and Shipping Instructions sheet
3. Consent Forms
4. The home urine collection kit

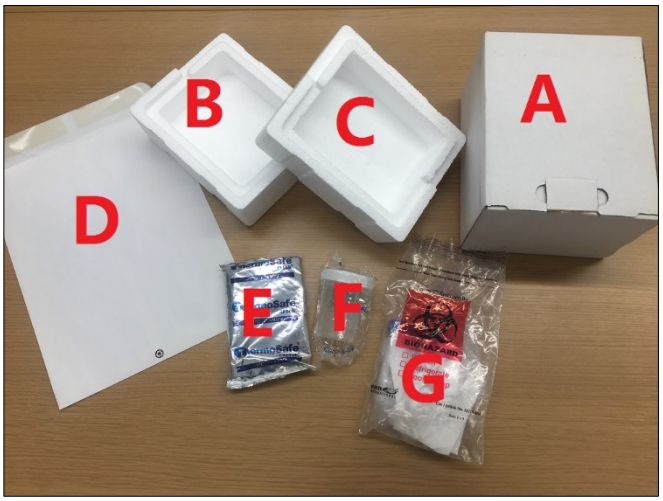
YOUR UNIQUE ID STICKER:

Your sticker is unique to you and it is found on:

1. The large white outer box
2. Your urine collection tube
3. The back of your return shipping envelope

Note: The sticker identifies your kit from kits assigned to other people. It's extremely important that you do not remove the Unique ID Stickers

HOME URINE COLLECTION KIT CONTENTS (NOTE, YOUR KIT CONTENTS MAY NOT EXACTLY MATCH PICTURE):



A. White cardboard outer box approx. 8.5 ”x 6.75” x 5.5” (22cm x 18cm x 14cm)
B. Styrofoam shipping container
C. Shipping container lid
D. FedEx UN3373 envelope
E. Refrigerant gel pack pouch
F. Plastic screw cap urine collection cup with your ID sticker
G. 2 Small zip closable bags, with 1 absorbent sheet and 1 tube in each bag. 2 extra absorbent sheets as back up

STEP 1: KIT PREPARATION:

1. Open the white cardboard box.
   (DO NOT throw this out as you will use it to return the sample)

2. Slide the Styrofoam shipping container out of the cardboard box.
   (DO NOT throw this out as you will use it to return the sample)

3. Open the Styrofoam container.

4. Remove the refrigerant gel pack pouch and place it in the freezer compartment of your home freezer for at least 6 hours.

5. Remove the smaller plastic bag with the plastic screw cap collection cup, and the Specimen bag from the Styrofoam container.

6. Remove the plastic screw cap collection cup from the small plastic bag

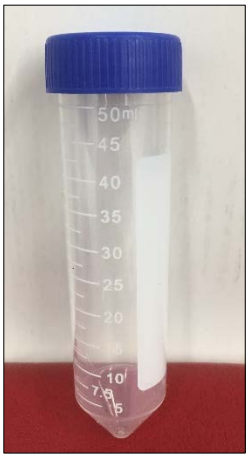
7. Remove the 2 tubes from the Specimen bag, then from the zip closable bag separately
   (DO NOT remove the 2 absorbent sheets from the zip closable bag)

STEP 2: COLLECT THE URINE SAMPLE:

Collect the sample when you first wake up for the day.

Mail the sample on the same day you collect the sample.

1. Before you collect your urine, verify that the ID sticker on the cup matches the ID sticker on the white outer box.
2. Wash hands with soap and water.
3. Take the cap off the cup before urinating.
4. Urinate (pee) into the collection cup until it is half full. The inside of the cup and cap should not touch or come into contact with any part of the body, clothing, or external surfaces.
5. Open the cap of the first tube.
   Pour urine from collection cup into tube until you reach the line marked 40 mL.
   DO NOT GO ABOVE THIS LINE.
6. Screw the top back on the tube tightly.
   Wipe the outside of the tube with a paper towel to remove any moisture or drips. **Repeat process with second tube.**
7. Discard any urine remaining in the collection cup in the toilet.
   Dispose of the collection cup in your trash.
   Wash your hands with soap and water.
8. Write the **date and time** you collected the urine on the label on sample collection card provided.



STEP 3: PACK THE URINE SAMPLE:

Pack the sample in the shipping container with the ice pack immediately after collection, even if you do not mail the package until later in the day.

1. Place the two tubes back into the zip closable bags separately with the absorbent sheets.
2. Push the air out of the zip closable bag and securely seal the bag.
3. Place the sealed bag into the Styrofoam container.
4. Place the frozen gel pack from your freezer into the Styrofoam container.
5. Do not include the used collection cup into the box.

Step 4: Pack the Urine Sample *continued*:

6. Place the Styrofoam lid onto the top of the Styrofoam bottom.
7. Slide the Styrofoam container into the white cardboard outer box, fold the flaps down, and tuck in the tabs.

8. Place the white outer box inside the FedEx UN3373 return shipping envelope.
9. Remove the adhesive strip from the shipping envelope, fold the edge over, and seal shut.
10. Complete sections 1 and 8 on the FedEx Intra-Canada Air Waybill form. Insert the form into the shipping documentation envelope and affix onto the Fed Ex Express UN3373 Pack.

STEP 5: SHIP THE URINE SAMPLE:

Use your local courier company (Fed Ex) to send the package.

The best way to send the package is to take it with the prepaid postage label to your nearest local courier location. Please drop off before 1PM.

You may search the nearest drop off location on the Fed Ex website at:
https://www.fedex.com/locate/index.html?locale=en_CA

NOTE: if you wish to have FedEx pick up the package, you will need to arrange this a few days ahead of time, and do the collection on the day they will arrive for pickup.

If you have any questions, please call 519-888-4567 ext. 33597 or email itc@uwaterloo.ca.

SAMPLE COLLECTION CARD

ID number [affix sticker here]:

DATE OF COLLECTION: _____ / _____ / _____ (YY/MM/DD)

TIME OF COLLECTION: _____am / pm

Please place this card in the box with your sample before sealing.

Reminder: When shipping back the sample to us, please do not include the signed consent in this package. Signed consent form should be sent separately in another return envelope.

APPENDIX 2.2: URINE COLLECTION SHIPPING INSTRUCTIONS, JAPAN

INSTRUCTIONS: "WHAT TO DO"

Urine Collection and Shipping Instructions

JAPAN

Collect a urine sample and ship it to the laboratory using these instructions.
Collect your urine sample as soon as possible - ideally within the next 5 days. However, if you cannot collect it within 5 days then please collect and ship it as soon as possible.
We will deposit 8000 e-points into your account within 8 weeks after we receive the package.

THE BAG YOU RECEIVED INCLUDES:

5. Large envelope that contains the collection kit, and your unique ID sticker
6. "WHAT TO DO" Urine Collection and Shipping Instructions sheet
7. Information Letter and Consent Forms
8. The home urine collection kit

YOUR UNIQUE ID STICKER:

Your sticker is unique to you and it is found on:

4. The large white outer box
5. Your urine collection tube
6. The back of your return shipping envelope

Note: The sticker identifies your kit from kits assigned to other people. It's extremely important that you do not remove the Unique ID Stickers

HOME URINE COLLECTION KIT CONTENTS (NOTE, YOUR KIT CONTENTS MAY NOT EXACTLY MATCH PICTURE):

H. White cardboard outer box approx. 8.5" x 6.75" x 5.5" (22cm x 18cm x 14cm)
I. Styrofoam shipping container
J. Shipping container lid
K. White return shipping envelope with Exempt Human Specimen, picture sticker, and

prepaid postage labels

L. Refrigerant gel pack pouch

M. Plastic screw cap urine collection cup

N. 2 Small zip closable bags, with 1 absorbent sheet and 1 tube in each bag. 2 extra absorbent sheets as back up

STEP 1. KIT PREPARATION:

1. Remove kit from the large zip closable bag.
2. Open the white cardboard box.
   (DO NOT throw this out as you will use it to return the sample)

3. Slide the Styrofoam shipping container out of the cardboard box.
   (DO NOT through this out as you will use it to return the sample)

4. Open the Styrofoam container.

5. Remove the refrigerant gel pack pouch and place it in the freezer compartment of your home freezer for at least 6 hours.

6. Remove the smaller plastic bag with the plastic screw cap collection cup, and the Specimen bag from the Styrofoam container.

7. Remove the plastic screw cap collection cup from the small plastic bag

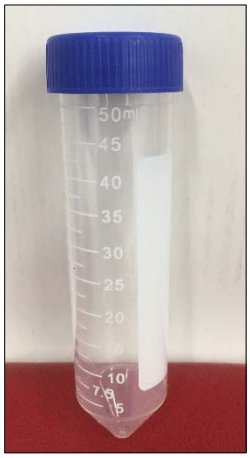
8. Remove the 2 tubes from the Specimen bag, then from the zip closable bag separately
   (DO NOT remove the 2 absorbent sheets from the zip closable bag)

STEP 2: COLLECT THE URINE SAMPLE:

Collect the sample when you first wake up for the day.

Mail the sample on the same day you collect the sample.

9. Before you collect your urine, verify that the ID sticker on the cup matches the ID sticker on the white outer box.
10. Wash hands with soap and water.
11. Take the cap off the cup before urinating.
12. Urinate (pee) into the collection cup until it is half full. The inside of the cup and cap should not touch or come into contact with any part of the body, clothing, or external surfaces.
13. Open the cap of the first tube.
    Pour urine from collection cup into tube until you reach the line marked 40 mL.
    DO NOT GO ABOVE THIS LINE.
14. Screw the top back on the tube tightly.
    Wipe the outside of the tube with a paper towel to remove any moisture or drips.
    Repeat process with second tube.
15. Discard any urine remaining in the collection cup in the toilet.
    Dispose of the collection cup in your trash.
    Wash your hands with soap and water.
16. Write the **date and time** you collected the urine on the label on sample collection card provided.



STEP 3: PACK THE URINE SAMPLE:

Pack the sample in the shipping container with the ice pack immediately after collection, even if you do not mail the package until later in the day.

Include the signed Consent Form but do not include these instructions, the cover letter, or the large zip closable bag with your name in the shipping envelope. Do not add additional packaging.

11. Place the two tubes back into the zip closable bags separately with the absorbent sheets
12. Push the air out of the zip closable bag and securely seal the bag.
13. Place the sealed bag into the Styrofoam container.
14. Place the frozen gel pack from your freezer into the Styrofoam container.
15. Do not include the used collection cup into the box.

Step 4: Pack the Urine Sample *continued*:

16. Place the Styrofoam lid onto the top of the Styrofoam bottom.
17. Slide the Styrofoam container into the white cardboard outer box, fold the flaps down, and tuck in the tabs.
18. Verify that the unique ID sticker on the shipping envelope matches the ID sticker on the white outer box
19. Place the white outer box inside the white return shipping envelope.
20. Remove the adhesive strip from the shipping envelope, fold the edge over, and seal shut.

STEP 5: SHIP THE URINE SAMPLE:

Use your local courier company (SAGAWA) to send the package.

The best way to send the package is to take it with the sealed prepaid postage label to your nearest local courier location.

You may search the nearest drop off location on SAGAWA's website http://www.sagawa-exp.co.jp/

NOTE: if you wish to have SAGAWA pick up the package, you will need to arrange this a few days ahead of time, and do the collection on the day they will arrive for pickup.

If you have any questions, please send your inquiries to https://jp.m.aipsurveys.com/inquiry.

SAMPLE COLLECTION CARD

ID number [affix sticker here]:

DATE OF COLLECTION: _____ / _____ / _____ (YY/MM/DD)

TIME OF COLLECTION: _____am / pm

Please place this card in the box with your sample before sealing.

Reminder: When shipping back the sample to us, please do not include the signed consent in this package. Signed consent form should be sent separately in another return envelope.

APPENDIX 3.1: RESPONDENT INFORMATION LETTER AND CONSENT FORM, CANADA

Research Project: Exposure to Toxicants from Vaporised Nicotine Products
Research Ethics Committee, University of Waterloo: ORE # 23064
Roswell Park Comprehensive Cancer Center IRB Clearance #: BDR 101218

Dear Participants,

****Please read this information and consent forms carefully**

Recently, you participated in an online survey on tobacco use from the International Tobacco Control Policy Evaluation (ITC) Project sponsored by the University of Waterloo, Canada, Roswell Park Comprehensive Cancer Center, US, and Medical University of South Carolina, US, and operated by Rakuten Insight / University of Waterloo. When you participated in the online survey, you also indicated that you were willing to provide us with your urine sample. This kit will be used to collect your urine sample and send it back to our lab for analysis.

Why and what we are asking of you?
The ITC Project is conducting a study to determine what chemicals are absorbed in the body for people who use different types of tobacco and nicotine products. After you inhale nicotine and other chemicals from tobacco products, these chemicals are processed by your body and eliminated in your urine. We want to measure these chemicals in your urine to estimate how much nicotine and other chemicals you have inhaled. Tobacco-related chemicals detected in urine do not indicate disease or risk for disease.

If you are not a smoker or a user of any products, the chemicals in your urine will be used as a comparison to those who do.

Possible Benefits
This study would help the researchers to evaluate and understand the effects of cigarette smoking and the use of novel nicotine-delivery devices such as e-cigarettes and heated tobacco products. By collecting your urine sample, we hope to learn more about exposures to tobacco-related chemicals in the population. This may be helpful to regulatory bodies around the world as they work to address new tobacco products.

Safety Note/Risk
Collection of urine is safe and will not cause any discomfort. Many studies with children and adults have used home urine collection kits.

Remuneration
When you send us back your urine sample as well as the signed consent form separately, we will provide you 25.00 CAD for the survey you had completed earlier, together with 125.00 CAD bonus incentives for sending back your urine sample and consent form. Please note if your urine sample and consent form are not received, you will not be eligible for the 150.00 CAD. All incentives will be provided within 8 weeks after we received your urine sample.

Frequently Asked Questions

1. **What am I supposed to do with this package?**

We are asking you to provide a urine sample using the enclosed kit provided. Your participation is voluntary.

Inside the package you will find …….

- "What to do" Urine Collection and Shipping Instruction sheet
- Informed consent document (a signed copy to be mailed separately from the urine sample and a copy for you to keep)
- White cardboard outer box
- Styrofoam shipping container
- Refrigerant gel pack pouch
- Plastic screw cap collection cup
- Zip-lock bag with absorbent sheet and two tubes with unique ID sticker on them
- White return shipping envelope with Human Exempt and postage paid labels for sending your urine sample
- A smaller white mailing envelope with prepaid postage labels for sending your signed consent form.

For details on how to use this package, please read <INSTRUCTIONS: "WHAT TO DO" - Urine Collection and Shipping Instruction>

2. **What should I do with the ice pack?**

Before collecting the urine, place the ice pack in your freezer overnight (or at least 6 hours).

3. **What am I supposed to do with the cup?**

You will use the cup to collect the urine specimen. Please read and follow the instructions on the "What to do" Urine Collection and Shipping Instruction sheet provided with the kit.

4. **When should I complete the home urine collection and mail the box?**

As soon as you received the kit and after you freeze the ice pack for at least 6 hours. See below #5 for the time of day for collection. **Do not fill the urine cup unless you can mail the box on the same day**. Bring to FedEx drop location or pre-arrange for FedEx pickup as soon as possible after collection. When we receive the box, we will send you $25 for the completion of the online survey as well as $125 for the urine sample.

5. **Is there a special time of day to collect the specimen?**

This is very important. For **tobacco product users**, you should urinate (pee) into the cup **first thing in the morning when you wake up** and **before you use any tobacco product.**
For **non-smokers or non-users**, please also urinate (pee) into the cup **first thing in the morning when you wake up**.

6. **What do I do after I have urinated (peed) into the cup?**

You will pour from the larger cup into 2 smaller tubes (see Instructions). You may flush away any leftover urine, and wash and throw away the cup. DO NOT overfill the tubes – leave an air space of about 1 inch (2 cm) below the top of the tube before sealing. Also DO NOT add water or anything else to the urine. Then package the tubes as shown in the instructions.

7. **Should I write my name on the sample?**

To protect your privacy, **please DO NOT write your name on the tubes, envelope, or any other part of the kit.** You are provided with stickers containing an ID number. These will help us link your sample to survey responses.

8. **Should I provide urine sample if I have one of the following conditions:**
    a. I am currently on a diuretic medication
    b. I am currently on antibiotics
    c. I am currently on prescription medication for various conditions, e.g., medication for high blood pressure
    d. [For women] I currently have my period

The answer is **YES**, you can provide your urine sample and should not wait.

9. **What happens to my sample after I send it in?**

The sample will be sent to the University of Waterloo in Waterloo Ontario, where it will be stored in a -20 degree Celsius freezer until all urine samples have been collected. Once collection is complete, the samples will be sent to the Roswell Park Comprehensive Cancer Center in Buffalo, New York where it will be analysed for chemical components related to your tobacco use, or lack thereof. Analysis of samples will take place over 6 months after which all samples will be disposed of.

10. **Do I send my sample and consent forms separately?**

Yes, we provide two separate envelopes for you to send both your sample and your consent separately. Your Urine sample should be shipped in the envelope with the Human Exempt label. The consent form should be mailed in the smaller envelope. This is to ensure that your sample and your consent form are not linked to one another.

11. **Can I withdraw my sample at any time within 6 months after you sent us the samples ?**

Yes. If you would like to have your sample removed from the study at any time, please contact us at 519-888-4567 ext. 33597 or itc@uwaterloo.ca expressing your desire to have the sample removed. Please note that your urine sample will be disposed after 6 months when the analysis is done.

12. **What are researchers looking for with the collected samples?**

Analysts seek to determine what chemicals are absorbed by the body when people use different types of tobacco or nicotine products. After you inhale nicotine and other chemicals from tobacco products, these chemicals are processed by your body and eliminated in your urine. We seek to measure these chemicals in your urine to estimate how much nicotine and other chemicals you have inhaled. Samples of non-users will also be measured for comparison. Chemicals detected in urine are not indicative of disease or risk of disease.

13. **Who do I contact if I have additional questions?**

University of Waterloo staff will answer any questions you have from Monday to Friday between 9:00 am and 4:00pm at 519-888-4567 ex. 33597 or by email at itc@uwaterloo.ca.

RESPONDENT CONSENT FORM (Your copy)

Research Project: Exposure to Toxicants from Vaporised Nicotine Products
Research Ethics Committee, University of Waterloo: ORE # 23064
Roswell Park Comprehensive Cancer Center IRB Clearance #: BDR 101218

By signing this consent form, I am not waiving my legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

I agree to take part in the above international research project and I have read the information letter, which I will keep for my records. I have been informed that:

- This project is being conducted for research purposes.
- Participation in the research is voluntary and that I am free to withdraw at any time or to withdraw any information previously supplied.
- All the information I provide will not be linked back to me, subject to legal requirements and limitations.

For the urine sample quality control purposes, please answer these essential questions:

When was the last time you used any of the following products?
Please circle one response per product.

	Less than 1 hour ago	1-6 hours ago	7-12 hours ago	12-24 hours ago	More than 24 hours ago	Do not use this product
Ordinary Cigarette	1	2	3	4	5	6
iQOS	1	2	3	4	5	6
E-cigarette	1	2	3	4	5	6

I give my consent to provide my urine sample for this research.

ID number [affix sticker here]:

Signature: ……

Date: ……/……../……...(DD/MM/YYYY)

Contact Information:

If you have any questions regarding the instructions, please contact us at [1-800-361-2902. Local: 416-391-5900 or recruiting.info@crcresearch.com]. If you contact us via email, we will get

back to you as soon as possible. Please leave a detailed message about the problem, including any details about the browser you are using and the error message (if any) you are seeing..

The project is led by: Geoffrey T. Fong, Ph.D., Principal Investigator: Tel: +1-519-888-4567 ext. 33597, Email: geoffrey.fong@uwaterloo.ca, University of Waterloo, Waterloo, Ontario, Canada.

This project has been reviewed and has received ethics clearance from the University of Waterloo, Canada. The contact information is The Chief Ethics Officer, Office of Research Ethics at: 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

RESPONDENT CONSENT FORM
(Enclose this completed copy with your urine sample)

Research Project: Exposure to Toxicants from Vaporised Nicotine Products
Research Ethics Committee, University of Waterloo: ORE # 23064
ROSWELL PARK COMPREHENSIVE CANCER CENTER IRB CLEARANCE #: BDR 101218

By signing this consent form, I am not waiving my legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

I agree to take part in the above international research project and I have read the information letter, which I will keep for my records. I have been informed that:

- This project is being conducted for research purposes.
- Participation in the research is voluntary and that I am free to withdraw at any time or to withdraw any information previously supplied.
- All the information I provide will not be linked back to me, subject to legal requirements and limitations.

For the urine sample quality control purposes, please answer these essential questions:

When was the last time you used any of the following products?
Please circle one response per product.

	Less than 1 hour ago	1-6 hours ago	7-12 hours ago	12-24 hours ago	More than 24 hours ago	Do not use this product
Ordinary Cigarette	1	2	3	4	5	6
iQOS	1	2	3	4	5	6
E-cigarette	1	2	3	4	5	6

I give my consent to provide my urine sample for this research.

ID number [affix sticker here]:

Signature: ……

Date: ……../……../……..…..(DD/MM/YYYY)

Contact Information:

If you have any questions regarding the instructions, please contact us at [1-800-361-2902. Local: 416-391-5900 or recruiting.info@crcresearch.com]. If you contact us via email, we will get back to you as soon as possible. Please leave a detailed message about the problem, including any details about the browser you are using and the error message (if any) you are seeing..

The project is led by: Geoffrey T. Fong, Ph.D., Principal Investigator: Tel: +1-519-888-4567 ext. 33597, Email: geoffrey.fong@uwaterloo.ca, University of Waterloo, Waterloo, Ontario, Canada.

This project has been reviewed and has received ethics clearance from the University of Waterloo, Canada. The contact information is The Chief Ethics Officer, Office of Research Ethics at: 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca.

APPENDIX 3.2: RESPONDENT INFORMATION LETTER AND CONSENT FORM, JAPAN

Research Project: Exposure to Toxicants from Vaporised Nicotine Products
Research Ethics Committee, University of Waterloo: ORE # 23064
Roswell Park Comprehensive Cancer Center IRB Clearance #: BDR 101218

Dear Participant,

****Please read this information and consent forms carefully**

Recently, you participated in an online survey on tobacco use from the International Tobacco Control Policy Evaluation (ITC) Project sponsored by the University of Waterloo, Canada, Roswell Park Comprehensive Cancer Center, US, and Medical University of South Carolina, US, and operated by Rakuten Insight. When you participated in the online survey, you also indicated that you were willing to provide us with your urine sample. This kit will be used to collect your urine sample and send it back to our lab for analysis.

Why and what we are asking of you?
The ITC Project is conducting a study to determine what chemicals are absorbed in the body for people who use different types of tobacco and nicotine products. After you inhale nicotine and other chemicals from tobacco products, these chemicals are processed by your body and eliminated in your urine. We want to measure these chemicals in your urine to estimate how much nicotine and other chemicals you have inhaled. Tobacco-related chemicals detected in urine do not indicate disease or risk for disease.

If you are not a smoker or a user of any products, the chemicals in your urine will be used as a comparison to those who do.

Possible Benefits
This study would help the researchers to evaluate and understand the effects of cigarette smoking and the use of novel nicotine-delivery devices such as e-cigarettes and heated tobacco products. By collecting your urine sample, we hope to learn more about exposures to tobacco-related chemicals in the population. This may be helpful to regulatory bodies around the world as they work to address new tobacco products.

Safety Note/Risk
Collection of urine is safe and will not cause any discomfort. Many studies with children and adults have used home urine collection kits.

Remuneration
Once we receive your urine sample and the signed consent form, we will provide you [2000 e-points] for the survey you had completed earlier, together with [8000 e-points] bonus incentives for sending back your urine sample and consent form. If you only completed the survey but do not send us your urine samples and consent form, you will only be getting [2000 e-points]. All incentives will be provided within 8 weeks after we received your urine sample.

Frequently Asked Questions

14. What am I supposed to do with this package?

We are asking you to provide a urine sample using the enclosed kit provided. Your participation is voluntary.

Inside the package you will find …….

- "What to do" Urine Collection and Shipping Instruction sheet (including Sample collection card to be shipped back with urine sample)
- Informed consent document (a signed copy to be mailed separately from the urine sample and a copy for you to keep)
- White cardboard outer box
- Styrofoam shipping container
- Refrigerant gel pack pouch
- Plastic screw cap collection cup
- Zip-lock bag with absorbent sheet and two tubes with unique ID sticker on them
- Yellow return shipping envelope with prepaid postage labels for sending your urine sample
- A smaller white mailing envelope with prepaid postage labels for sending your signed consent form.

For details on how to use this package, please read <INSTRUCTIONS: "WHAT TO DO" - Urine Collection and Shipping Instruction>

15. What should I do with the ice pack?

Before collecting the urine, place the ice pack in your freezer overnight (or at least 6 hours).

16. What am I supposed to do with the cup?

You will use the cup to collect the urine specimen. Please read and follow the instructions on the "What to do" Urine Collection and Shipping Instruction sheet provided with the kit.

17. When should I complete the home urine collection and mail the box?

As soon as you received the kit and after you freeze the ice pack for at least 6 hours. See below #5 for the time of day for collection. **Do not fill the urine cup unless you can mail the box on the same day**. Bring to [SAGAWA] drop location or pre-arrange for [SAGAWA] pickup as soon as possible after collection. When we receive the box, we will deposit [2000 e-points] in appreciation for the survey completion and [8000 e-points] for the urine sample into your account. If you only completed the survey but do not send us your urine samples and consent form, you will only be getting [2000 e-points]. All incentives will be provided within 8 weeks after we received your urine sample.

18. Is there a special time of day to collect the specimen?

This is very important. For **tobacco product users**, you should urinate (pee) into the cup **first thing in the morning when you wake up** and **before you use any tobacco product.**
For **non-smokers or non-users**, please also urinate (pee) into the cup **first thing in the morning when you wake up**.

19. What do I do after I have urinated (peed) into the cup?

You will pour from the larger cup into 2 smaller tubes (see Instructions). You may flush away any leftover urine, and wash and throw away the cup. DO NOT overfill the tubes – leave an air space of about 2 cm below the top of the tube before sealing. Also DO NOT add water or anything else to the urine. Then package the tubes as shown in the instructions.

20. Should I write my name on the sample?

To protect your privacy, **please DO NOT write your name on the tubes, envelope, or any other part of the kit**. You are provided with stickers containing an ID number. These will help us link your sample to survey responses.

21. Should I provide urine sample if I have one of the following conditions:

a. I am currently on a diuretic medication
b. I am currently on antibiotics
c. I am currently on prescription medication for various conditions, e.g., medication for high blood pressure
d. [For women] I currently have my period

The answer is **YES**, you can provide your urine sample and should not wait.

22. What happens to my sample after I send it in?

The sample will be sent to our storage facility in Tokyo, where it will be stored in a -20 degree Celsius freezer until all urine samples have been collected. Once collection is complete, the samples will be sent to the Roswell Park Comprehensive Cancer Center in Buffalo, New York where it will be analysed for chemical components related to your tobacco use, or lack thereof. Analysis of samples will take place over 6 months after which all samples will be disposed of.

23. Do I send my sample and consent forms separately?

Yes, we provide two separate envelopes for you to send both your sample and your consent separately. Your Urine sample should be shipped in the envelope. The consent form should be mailed in the smaller envelope. This is to ensure that your sample and your consent form are not linked to one another.

24. Can I withdraw my sample at any time within 6 months after you sent us the samples ?

Yes. If you would like to have your sample removed from the study at any time, please contact us at [https://jp.m.aipsurveys.com/inquiry] expressing your desire to have the sample removed. Please note that your urine sample will be disposed after 6 months when the analysis is done.

25. What are researchers looking for with the collected samples?

Analysts seek to determine what chemicals are absorbed by the body when people use different types of tobacco or nicotine products. After you inhale nicotine and other chemicals from tobacco products, these chemicals are processed by your body and eliminated in your urine. We seek to measure these chemicals in your urine to estimate how much nicotine and other chemicals you have inhaled. Samples of non-users will also be measured for comparison. Chemicals detected in urine are not indicative of disease or risk of disease.

26. Who do I contact if I have additional questions?

[Rakuten Insight] staff will answer any questions you have by email at [https://jp.m.aipsurveys.com/inquiry].

RESPONDENT CONSENT FORM (Your copy)

Research Project: Exposure to Toxicants from Vaporised Nicotine Products
Research Ethics Committee, University of Waterloo: ORE # 23064
Roswell Park Comprehensive Cancer Center IRB Clearance #: BDR 101218

By signing this consent form, I am not waiving my legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

I agree to take part in the above international research project and I have read the information letter, which I will keep for my records. I have been informed that:

- This project is being conducted for research purposes.
- Participation in the research is voluntary and that I am free to withdraw at any time or to withdraw any information previously supplied.
- All the information I provide will not be linked back to me, subject to legal requirements and limitations.

For the urine sample quality control purposes, please answer these essential questions:

When was the last time you used any of the following products?
Please circle one response per product.

	Less than 1 hour ago	1-6 hours ago	7-12 hours ago	12-24 hours ago	More than 24 hours ago	Do not use this product
Ordinary Cigarette	1	2	3	4	5	6
iQOS	1	2	3	4	5	6
Glo	1	2	3	4	5	6
Ploom TECH	1	2	3	4	5	6

I give my consent to provide my urine sample for this research.

ID number [affix sticker here]:

Signature: ……

Date: ……..…./……..…../……....(YYYY/MM/DD)

Contact Information:

If you have any questions regarding the instructions, please notify https://jp.m.aipsurveys.com/inquiry and we will get back to you as soon as possible. Please leave a detailed message about the problem.

The project is led by:

Geoffrey T. Fong, Ph.D., Principal Investigator: Tel: +1-519-888-4567 ext. 33597, Email: geoffrey.fong@uwaterloo.ca, University of Waterloo, Waterloo, Ontario, Canada.

This project has been reviewed and received ethics clearance from a University of Waterloo, Canada, Research Ethics Committee. The contact information is Office of Research Ethics at: 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca. Please include the ethics # provided above in your email.